

5 **FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE**
ORAL DOSAGE FORM USING IN VITRO DISINTEGRATION TEST DATA

10 Erodible, gastric-retentive dosage forms are provided that are formulated using the
in vitro drug release profile obtained with USP Disintegration test equipment rather the
USP Dissolution Apparatus. The invention is premised on the discovery that the USP
Disintegration Test and modified versions thereof are far more predictive of the *in vivo*
release profile for a controlled release dosage form than is the standard USP Dissolution
15 Test, particularly controlled release dosage forms of the swellable, erodible type. The
dosage forms generally comprise particles of a biocompatible, hydrophilic polymer having
the active agent incorporated therein, wherein the particles are optionally but preferably
compacted into a tablet or loaded into a capsule. The dosage forms can be used to deliver
water-insoluble or sparingly soluble drugs as well as water-soluble drugs, providing that
20 the latter are coated with a protective coating or contained in a protective vesicle.